

EDITORIAL

Critical Appraisal of a Manuscript

When asked to review a manuscript, I usually go to the title first and then the abstract to obtain an overall feel for the topic. Then I proceed to read the body of the manuscript in order to critically appraise it. I wish to be fair in my appraisal and not be governed by my own bias' regarding the topic. Consequently, I have developed over the years a structured approach to critically appraising a manuscript using geometrical designs to assist me.

In a series of editorials over the next few issues of HPB, I am going to share with the readers a way of critically appraising a manuscript or a study using the geometrical approach. This approach has been developed following reading and suggestions from a variety of notable authors who have written extensively on this topic. I reference some of these publications at the end of this initial editorial.

The crux of the geometrical approach is based on subdividing the study into three major components as illustrated by a triangle, a circle and square (Figure 1). This is called the PECOT Diagram. Each of the letters being representative of the components of a typical clinical study.

PECOT

Using the geometrical design as an aid a clinical study may be subdivided into the following components.

Population: Within the triangle should be placed the population being studied. Any clinical study has a group of subjects who are representative of the population at large, having the condition which is being studied. Consequently, thoughts and criticisms regarding the population being studied can be

grouped within the triangle, thus helping the reviewer focus the criticism on the population selected.

Intervention and Comparison: Within the circle the intervention or exposure against a comparison is categorised. There may be more than one exposure or there may just be one that is compared against a control or another exposure. The circle is subdivided in a manner which illustrates what is being done and what it is compared against.

Outcomes: The results of the exposure or exposures against the comparison are then recorded in the square which is designed to illustrate positive or negative outcomes as a result of the exposure, when compared with the comparison. There may just be a single outcome, or there may be a number of outcomes which can be categorised in a linear fashion against the exposure and the comparison.

Time: Finally the last component of the PECOT diagram is the time component which needs to be specified. In other words, is the study confined to events that are analysed at one point in time after the exposure and comparison? Or is it a continual change which is being accessed over a longer period of time?

Study Validity

Having defined all of the components of the PECOT diagram, it is now time to revisit each one of these to assess whether the components are well designed (i.e. in other words, are absent of bias). Bias (or systematic error) is one of the major bugbears of clinical studies. It is extremely difficult to remove bias from clinical studies, however it is important to be able to define the level of bias so that the results and ultimately the conclusions that we draw from any study can be evaluated in the context of this knowledge.

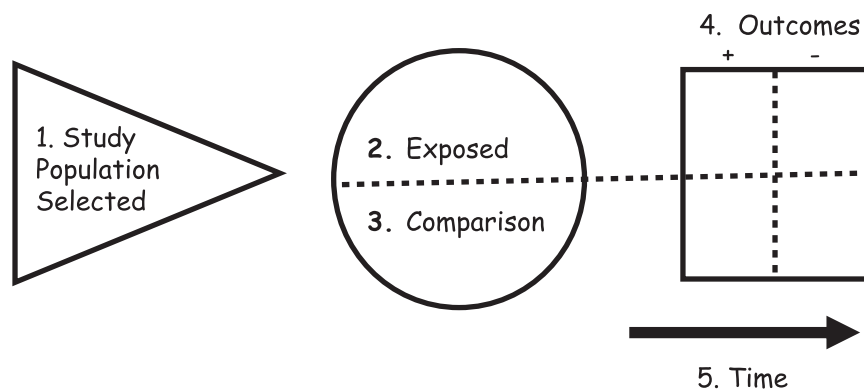


Figure 1. PECOT diagram: design components.

I refer you back to the PECOT diagram in order to appraise any manuscript in order to determine the degree if any of bias.

Selection Bias: Look to the triangle which defines the study population. Now ask the question whether the population being studied truly represents the general population with the condition which is being studied. Is the study population representative of the source population? For instance, if we were to study Gallstone Disease then to represent the population at large we would need to go out into the community to select our study population. If we were to make our selection only from patients who presented to a hospital we would be biasing our selection. Of course there is nothing wrong with basing a study on Gallstone Disease only on a population that presents to a hospital. However, the conclusions that we would draw from such a selection can only refer to that population and not to the general population in the community. Consequently, in critically appraising a manuscript do ask the question whether the population that has been selected is truly representative of what the researchers aim to study.

Confounder: Confounding bias occurs at the next geometric component (i.e. the circle). The confounder is another type of treatment which might influence the exposure and/or the comparison. There is a famous study which was conducted on post menopausal women placed on hormone replacement therapy. It was noted in a cohort study of women on hormone replacement therapy that the prevalence of heart attacks was lower when compared with the general population of post menopausal women not placed on hormone replacement therapy. However, on closer analysis of the population being studied it was also noted that women who had been placed on hormone replacement therapy were also the type of women who tended to have healthier lifestyles, would be of normal weight and would include physical exercise as part of their daily routine. When this component or this confounder was removed from the equation, it was noted that hormone replacement therapy had little or no effect on the prevalence of subsequent heart attack in the population of post menopausal women.

The way that we remove confounders in a clinical study is to prospectively randomise the population that is being studied. This is why prospective randomised studies are thought of so highly in the medical/clinical literature. When done appropriately, it is the most powerful means of removing confounders which may influence the results of the treatment being tried.

A number of other confounders may arise and it is important when reviewing a manuscript to look for these or at least ask the question which to an experienced clinician an obvious answer may exist. Have there been any other interventions in any of the groups?

Measurement Bias: This occurs in both the circle and the square of outcomes. It is important when critically appraising a manuscript to ensure that there has not been any bias in the measurement of the exposures, the comparisons or any of the outcomes. In other words the numbers need to add up and be consistent with what was intended on the outset. If the numbers do not add up then it is necessary for the investigators to have accounted for the differences. Such differences in the numbers might be produced if individuals have been lost in follow up or if unexpected deaths have occurred etc. A good study will account for every individual entered into the study.

Measurement Bias may also occur by what is known as compliance or contamination of the numbers. This is where patients who were intended to have one type of intervention as opposed to another receive the wrong intervention. Consequently, the numbers are contaminated by this fault in the study.

As can be seen from the above I have to at this stage not used any numbers, formulae or statistics. What I have done is use the geometrical designs illustrated in the figure to subdivide any study according to its components. The PECOT diagram is a geometrical way of doing this and assists me in critically appraising any study.

In subsequent issues of the Journal, I will use the editorial pages to talk about the use of numbers, what they mean to a clinician and how one can use this type of approach to not only critically appraise a manuscript for a journal such as HPB, but to also teach our colleagues and students.

Jim Toouli
Editor-in-Chief

Recommended References

- [1] Guyatt GH, Sackett DL, Cook DJ. User's guide to the medical literature. II How to use an article about therapy or prevention. A. Are the results of the study valid? JAMA 1993;270:2598–601.
- [2] Guyatt GH, Sackett DL, Cook DJ. User's guides to the medical literature. II How to use an article about therapy or prevention. B. What were the results and will they help me in caring for my patients? JAMA 1994;271:59–63.